



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,249	08/28/2003	Michael M. Neff	WSHU 2064.I	7302
321 7590 SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			EXAMINER BAUM, STUART F	
			ART UNIT 1638	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		01/08/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/08/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/650,249	NEFF, MICHAEL M.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 September 2006.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13, 15-65 and 67-88 is/are pending in the application.
 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 13, 15-21, 31, 43, 46, 53, 67-71, 74 and 76-79 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 28 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-12,22-30,32-42,44,45,47-52,54-65,72,73,75 and 80-88.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :pg 2 of 12 of IDS filed 4/20/04.

Art Unit: 1638

DETAILED ACTION

1. The amendment filed 9/22/2006 has been entered.

2. Claims 1-13, 15-65, 67-88 are pending.

Claims 1-12, 22-30, 32-42, 44-45, 47-52, 54-65, 72-73, 75, 80-88 have been withdrawn from consideration for being drawn to non-elected inventions.

Claims 14 and 66 have been canceled.

3. Claims 13, 15-21, 31, 43, 46, 53, 67-71, 74, and 76-79, including SEQ ID NO:1 are examined in the present office action.

4. Rejections and objections not set forth below are withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

6. This application contains claims 1-12, 22-30, 32-42, 44-45, 47-52, 54-65, 72-73, 75, 80-88 drawn to an invention nonelected with traverse filed 11/7/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Amendment Objection

7. The Office notes that claim 68 is amended but the claim status identifier recites "original" instead of --Currently Amended--. For purposes of compact prosecution, an action is set forth. In response to this action, Applicants are requested to correct the status identifier.

Claim Objection

8. Claim 67 is objected to for being dependent on a canceled claim.

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 16 recites a hybridization wash condition which is less stringent than the wash condition recited in the claim from which it is dependent.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 13 and 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

Claim 13 is indefinite for reciting "which encodes a polypeptide having activity differing from that of SEQ ID NO:1". SEQ ID NO:1 is a DNA sequence, not a polypeptide sequence.

Written Description

10. Claims 13, 16-21, 31, 43, 46, 53, 67-71, 74, and 76-79 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/24/2006. Applicant's arguments filed 9/22/2006 have been fully considered but they are not persuasive.

Applicants contend they have defined OBP according to SEQ ID NO:1 and sequences that hybridize under specific conditions and Applicants have required that the OBP in the claimed subject matter also have a requisite activity-namely, the ability to affect plant stature as described in the specification (page 25 of Remarks, 1st full paragraph). Applicants contend other sequences that affect OPB expression are disclosed (page 25 of Remarks, 2nd full paragraph).

The Office contends that for claims drawn to a transgenic plant cell transformed by an OBP antisense coding nucleic acid expression vector, wherein the expression vector comprises the OBP sequence of SEQ ID NO:1 in antisense orientation, the written description requirement is fulfilled. But, the Office contends that for claims drawn to sequences exhibiting less than 100% sequence identity to SEQ ID NO:1, Applicants have not fulfilled the written description requirement. Applicants have not disclosed a representative number of sequences that can be used in antisense orientation to downregulate the endogenous gene. Applicants also have not disclosed essential regions or conserved domains of SEQ ID NO:1 that are specific to the genus of sequences that when used as antisense molecules will downregulate or inhibit the expression of SEQ ID NO:1 or homologues thereof. In addition, Applicants have included a functional limitation for which the metes and bounds cannot and have not been determined, e.g., "having activity differing from that of SEQ ID NO:1 by about 40%, 30%, 20%, 10% or less". Therefore, the Office contends Applicants are not in possession of the broadly claimed invention.

Enablement

11. Claims 13, 15-21, 31, 43, 46, 53, 67-71, 74, and 76-79 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/24/2006. Applicant's arguments filed 9/22/2006 have been fully considered but they are not persuasive.

Applicants contend that sequences that hybridize to the 3' or 5' regions of SEQ ID NO:1, or the 35S promoter region of SEQ ID NO:1, and wherein said sequences in antisense orientation did not silence or down regulate the endogenous gene, would fall outside the scope of the claims. Applicants contend that the claims require both a particular structure and a particular function (page 26 of Remarks, 4th paragraph).

The Office contends that determining which sequences fall outside the scope of Applicants' claims or which sequences are encompassed by Applicants' claims requires undue trial and error experimentation. Applicants' claims recite hybridization conditions which would select sequences that do not work in Applicants' invention. Applicants have not disclosed how one skilled in the art can identify sequences that would be operable in the claimed invention. For instance, which sequence of bases are specific to Applicants' OBP DNA and can be used to down-regulate the endogenous gene. It is known in the art that antisense technology requires base pair complementarity between the antisense molecule and the target sequence. Applicants' claims are drawn to a multitude of sequences, with only a portion of those sequences being operable in Applicants' invention. One of skill in the art would have to screen through a

Art Unit: 1638

multitude of sequences to determine which sequences are operable in Applicants' invention.

Given the unpredictability, state-of-the-art, and breadth of the claims as discussed in the previous office action mailed 3/24/2006, one of skill in the art would require undue trial and error experimentation to practice the claimed invention.

Applicants contend they intentionally excluded the nucleic acid encoding the Dof domain from the construct that was used (page 27 of Remarks, 2nd paragraph). Applicants note that this fact was noted by the Office and Applicants contend this was done in order to prevent the very effect the Office contends would occur - namely, the down regulation of genes that affect phenotypes other than those affecting plant structure (*Ibid*). Therefore, Applicants contend Papi et al., who use proteins containing a Dof domain, is not indicative of the claimed invention (*Ibid*).

The Office contends Applicants are arguing limitations not specified in the claims. The claims are drawn in part to any nucleic acid that hybridizes under the specified conditions to SEQ ID NO:1. Applicants' arguments are not commensurate in scope with the claimed invention and although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants again contend that sequences that do not meet the structural and functional requirements fall outside the scope of the claimed invention and need not be enabled (page 27 of Remarks, 3rd paragraph).

The Office has addressed this issue above.

Applicants contend the Colliver et al reference discloses that heterologous sequences can be used to down regulate an endogenous gene assuming the heterologous sequence and endogenous sequence share at least a certain percent homology (page 28 of Remarks, 1st paragraph). Applicants contend Faske et al (1997, Plant Physiol. 115:705-715) state "it has been shown previously that silencing of endogenous genes can be similarly achieved by transformation with closely related but non-identical sequences (page 29 of Remarks, top paragraph).

The Office contends that Faske et al state "Similarly low NADP-MDH levels were not stable in all cosuppressed transgenic sense lines" (page 709, left column, top paragraph); "antisense transformants with NADP-MDH levels that were reduced to less than 13% of the wild type level were not obtained (page 709, left column, 1st full paragraph); "However, no good antisense effect was observed (Table 1)" (page 713, left column, 1st full paragraph). In addition, the data from Faske et al teach that the antisense effect was not stable (page 709, left column, 1st full paragraph). Therefore, even Faske et al teach antisense produces unpredictable results.

Applicants contend Bowie et al disclose proteins are surprisingly tolerant of amino acid substitutions (page 30 of Remarks, 2nd paragraph).

The Office contends that Bowie et al does teach unpredictability.

Applicants contend McConnell et al is not indicative of the enablement of Applicant's invention, as the substitutions disclosed therein are not conservative substitutions as required by Applicant's claims (page 32 of Remarks, top paragraph).

The Office contends that not all of Applicants' claims are directed to conservative substitutions. For example, claim 13 is drawn to a nucleotide sequence that hybridizes to SEQ ID NO:1.

Applicants contend enablement does not preclude any testing or experimentation, just undue testing or experimentation and Applicants contend determining whether antisense sequences would have the required structural and functional characteristics would fall within the realm of routine experimentation (page 32 of Remarks, 2nd full paragraph).

The Office contends Applicants' claims are drawn to a multitude of sequences, with only a portion of those sequences being operable in Applicants' invention. One of skill in the art would have to screen through a multitude of sequences to determine which sequences are operable in Applicants' invention. Given the unpredictability, state-of-the-art, and breadth of the claims as discussed in the previous office action mailed 3/24/2006, one of skill in the art would require undue trial and error experimentation to practice the claimed invention.

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1638

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
December 12, 2006

STUART F BAUM, PH.D
PRIMARY EXAMINER